



Bureau of Radiological Health
NH Department of Health & Human Services

Radiation Safety Topics

Writing a Podiatric Radiation Protection Program

Introduction

Since February 1, 1995, the New Hampshire Rules for the Control of Radiation (the Rules) have required each registrant "to develop, document, and implement a radiation protection program sufficient to ensure compliance with" the Rules. That requirement has been continued under the latest revisions.

This Radiation Safety Topics is intended to help podiatric x-ray registrants write their radiation protection programs. All requirements are established by state law and the Rules; there are no additional requirements here. This information cannot be a substitute for an understanding of the requirements of the Rules that apply to you; rather, it is intended as a "guide for the perplexed." In what follows, a radiation protection program is referred to as an RPP.

General points

In addition to the various annual dose limits set by the Rules, it is a key radiation safety practice and requirement (He-P 4020.04(b)) to keep exposures to radiation as low as reasonably achievable. That phrase is so constant a refrain in radiation safety that it has its own acronym: ALARA. This may be done through the application of procedures and engineering controls (e.g., minimizing exposure times, shielding) based on sound radiation protection principles. You may take economic and social factors into account in deciding what is reasonable. For instance, you need not take elaborate and expensive steps to reduce exposures effectively to zero, but on the other hand, dollars may not be the only criterion.

Not all of the following points may be applicable to your facility, equipment and operations. In that case, they don't have to be included in your RPP. On the other hand, the information here may not be sufficient for your needs. You should review your particular situation against the requirements of the Rules in order to assure compliance with them. If you decide a requirement in the Rules does not apply, it is appropriate to say so in your RPP, with a brief explanation as to why it is not applicable. This will indicate that you have considered the point.

The components of your RPP do not have to be in a stand-alone document. For instance, if you already have an OSHA compliance manual, you can build your RPP into it. However, all components of your RPP should be identifiable as such. The Bureau of Radiological Health will expect you to be able to identify and explain the parts of your program. Records of annual reviews of the contents of your RPP and how well it is working also need to be maintained for inspection. There is an appendix to this document listing portions of the Rules you may wish to become familiar with.

Writing a Podiatric Radiation Protection Program

If you don't have a copy of the New Hampshire Rules for the Control of Radiation we can provide them to you in printed form for \$10. This charge is to recover the costs of printing and mailing. Or you can send us a PC-compatible, 1.44 MB, 3.5 inch floppy disk and we will load the Rules on it and send it back. We can provide the files in WordPerfect 5.1 or MS Word formats. You do not have to get the Rules from us, but certain portions of them must be available to your employees (see section F below). If you want a copy of the Rules, send payment (for the printed version) to the address below, ask for the Rules, and tell us where you want the Rules sent.

NH Bureau of Radiological Health
6 Hazen Drive
Concord, NH 03301-6527

We ask that checks be made payable to: **Treasurer - State of New Hampshire.**

If you have questions about the Rules, registration of x-ray machines, radiation safety, or related points, please call us at 603-271-4588 or write to the address above. You can E-mail us at nhbrh@dhhs.state.nh.us. Comments about this *Radiation Safety Topics* and suggestions for others are welcome.

Contents of a Radiation Protection Program

Your RPP needs to address provisions of the Rules in Parts He-P 4020 through 4022. Not every provision applies to persons with x-ray machines. For instance, some sections of Part He-P 4020 do not apply to x-ray registrants, e.g., Section He-P 2040.07 on external dose from airborne radioactive material. Be careful, because there are some provisions that may apply to your situation that do not at first glance appear to. For instance, if an employee is occupationally exposed to radiation elsewhere, each registrant has to take into account that individual's total occupational exposure (He-P 4020.05(h)).

It is also reasonable for your RPP to address other parts and provisions of the Rules that apply to you. There are things in Parts He-P 4019, 4040, 4041, 4045, and 4046 that apply to podiatric facilities. Items relating to film processing are only one example.

One way to think about a radiation protection program is to consider it management's (your) plan for protecting employees and members of the public from radiation exposure and for complying with the Rules. Some things which might be a part of your RPP are:

A. Purpose of your RPP, authority, and access to information.

The goal of a radiation protection program is to keep radiation exposures to workers and the general public to levels as low as reasonably achievable (ALARA). Your RPP might specify:

- who is in charge of radiation safety at your facility;
- the goal of the RPP;
- your overall strategy for achieving radiation safety;
- where the RPP, procedures, equipment manuals, and records are kept; and
- the fact that these materials may be reviewed at any reasonable time.

A registrant is ultimately responsible for safety, but you may delegate the job to someone.

B. Operating procedures.

Having definite operating procedures can help keep everyone's exposure to radiation to low levels while still obtaining good quality images. You probably have developed procedures already. Now is an opportunity to review and improve them and to provide them to your people.

Sections He-P 4019.03 and 4045.03 require that workers be instructed in safe operating procedures. The provision in He-P 4019.03 is for posting or otherwise making available written operating procedures at the work location. See section F, "Posting and labeling" about the requirements for posting or otherwise making procedures available to workers. He-P 4045.03(e) requires you to provide "written safety procedures, including patient holding and any restrictions of the operating technique required for the safe operation of the particular system." You might identify what written procedures are available. A technique chart is also required to be posted and may be considered part of a procedure. See He-P 4045.03(d) for what a technique chart needs to contain.

Written procedures might also address such points as:

- where an operator is to stand when making an exposure;
- developing films;
- mixing, changing, and replenishing film processing solutions; and
- cleaning and maintaining film processing equipment.

C. Worker instruction.

In addition to any school training or previous experience your workers may have, the Rules require each registrant to instruct workers in site-specific facts, policies, and procedures relating to radiation safety. The instruction should be given to each new hire and probably at least annually thereafter. Your RPP might say who you hold responsible for providing the training or seeing that it is done. The instruction must include (per He-P 4019.04):

- that there is a source of radiation present and that its operation may pose some (typically small) risk to the operator and perhaps to others;
- instruction
 - a. in the risks inherent in the use of radiation, both to the worker and potential offspring;
 - b. in precautions and procedures to minimize exposure to radiation; and
 - c. about the purposes and function of protective devices used (e.g., collimators and "dead man" switches);
- that employees are to observe the Rules and your policies and procedures for radiation safety;
- that employees have a responsibility to report promptly to you or a named individual anything which may lead to unnecessary exposure or which is, or may lead to, a violation of the Rules, your policies, or procedures;
- notice of any radiation exposure reports due them under He-P 4019.05.

Your instruction should also include the explanations of terms used in the Rules (e.g., "declared pregnant woman", "dose") and the various applicable dose limits in He-P 4020 (e.g.,

embryo /fetal dose, eye dose, extremity dose). The extent of the instruction should be commensurate with the risks involved, which are typically small in podiatric practices.

The requirements for instructing workers which are in He-P 4019.04 are applicable to registrants of all kinds: dental, veterinary, industrial, medical, etc. For registrants whose operations involve x-rays for diagnostic purposes in the healing arts, there are additional requirements in He-P 4045.03. He-P 4045.03(b) says explicitly that operators are to be instructed in safe operating procedures and to be competent in the safe use of the x-ray equipment. Paragraph (c) in that same section then lists some important topics with which x-ray machine operators in the healing arts should be familiar. Paragraphs (e) and (f) then state that operators are to be provided with written safety procedures and that they need to be able to demonstrate that they are familiar with them. While these requirements are not strictly required to be a part of your RPP, it is reasonable for your RPP to encompass them.

It is a good idea to document the training you provide. The documentation might well be a simple statement of the date of the training, the topics covered, and names (possibly the signatures) of those trained.

D. Personnel monitoring (film or TLD badges).

The applicable occupational dose limits are given in He-P 4020.05 (for adults), 4020.11 (for minors), and 4020.12 (to a fetus from its mother's occupational exposure). He-P 4022.02(b) requires registrants to provide monitoring devices (e.g. film badges) only to those individuals who are occupationally exposed and likely to receive from external sources in one year doses exceeding 10 % of any applicable limit. In podiatric practices it is unlikely that workers will approach 10 % of any annual dose limit.

In any event, He-P 4020.04(b) requires you to keep exposures to radiation to levels "as low as reasonably achievable." Good radiation safety practices and ALARA considerations indicate:

- that x-ray machine operators be out of the useful x-ray beam during an exposure;
- that, no one, except the patient, be nearby while exposures are being made; and
- that anyone with the patient be provided with a shielding device (e.g., a leaded apron).

The doses actually received will depend on the distances involved, whether a barrier (shielding) is present, the technique factors used, and the number of exposures made over the course of a year. If you have previous dosimeter badge results or other measurements, they will help you to decide whether you need to provide badges to your workers.

Your RPP should say whether or not you will provide personnel monitoring (e.g., film or TLD badges) to your workers. If you intend to provide badges, there should be:

- some instruction in the RPP, a procedure, or the general instructions to employees as to where on the body to wear the badge (covered by Section He-P 4022.03;
- someone designated by name or title to be in charge of the badges;
- a location for the control badge where it is unlikely to be exposed accidentally;
- a statement of badge exchange frequency and how the exchange is to be accomplished; and

- information on how employees are to learn what their exposures have been (He-P 4019.05).

He-P 4003.01(aj) defines a "declared pregnant woman." This definition is used in Section He-P 4020.12. It requires you to maintain the dose to an embryo/fetus from occupational exposure of the mother below 500 millirem for the length of the pregnancy and to avoid substantial variation from month to month during that time.

There are details you should become familiar with. Among them is the fact that this section of the Rules applies only when a woman has voluntarily declared to you in writing that she is pregnant and has provided you with the estimated date of conception.

Fortunately, in a podiatric practice routine annual exposures should be well below 500 millirem; they may not even be detectable with film badges. This may make application of this provision of the Rules of no practical concern. Nevertheless, all women in your employ should be made aware of this provision of the Rules.

Another type of dosimetry is area monitoring. It cannot be used to assign doses to individuals, but it can tell you something of the radiation environment in which they work. It can be useful in determining compliance with dose limits to the public (see section G). You get badges from a dosimetry supplier but they are not assigned to individuals. Instead, they are placed in locations you wish to monitor for their long-term radiation levels. For instance, you might want to determine that a bookkeeper's office is adequately protected by the shielding of the x-ray room. You place the badge on the office side of the wall and let it stay there. After a few badge exchange cycles you will have direct, measured evidence you are meeting the dose limits for members of the public, or not, as the case may be. That data can be kept on file to demonstrate compliance. Please do not confuse a control badge with an area badge. A control badge needs to be kept in a location free from radiation exposure.

E. Quality assurance (QA) programs.

He-P 4045.07 has some requirements addressing film processing and handling. These requirements form the beginnings of a quality assurance program, but they are far from being a complete program. Your RPP should list any quality assurance programs for your x-ray equipment and film processing. For instance, do you have an annual, biennial, or other cycle for x-ray machine servicing? Or do you have a film processing QA program? No maintenance cycle or QA program is required by the Rules except for the provisions noted above. Detailed written procedures can be referred to. Either the RPP or the procedures should give:

- the intervals at which the QA steps are to be carried out;
- the actions to take if discrepancies are noted; and
- who is responsible for carrying out the various steps.

F. Posting and labeling.

As mentioned above, He-P 4019.03(b) through (g) have some posting requirements. Because they are part of the Rules, you need not incorporate them into your RPP. However, your RPP

might identify, where Form RHP-5, "Notice to Employees" is to be posted and who has been delegated the task of maintaining the posting and labeling. Review paragraphs He-P 4019.03(b) through (g) on posting requirements. Note the provision of He-P 4019.03(c) allowing you to post notices describing certain items and where they may be examined in lieu of posting the items themselves. Note also that Form RHP-5, "Notice to Employees" is an exception to that provision and must be posted conspicuously (see He-P 4019.03(d) and (g)).

He-P 4022.13(d) says "A room or area is not required to be posted with a caution sign because of the presence of radiation machines used solely for diagnosis in the healing arts." Therefore you are not under an obligation to post a "Radiation Area" or similar sign (He-P 4022.11 and 12) solely because of the presence and use of your x-ray equipment.

Certain labels are required by the Rules. He-P 4022.14(d) requires x-ray machines to be labeled in a conspicuous manner that radiation is produced when the equipment is energized. He-P 4046.01(a) and (b) require that the x-ray machine's control panel have another warning label. On newer machines the warnings are typically put there by the manufacturer.

All postings and labels should be reviewed from time to time. Any that are faded, worn, damaged, or defaced should be replaced or repaired.

G. Limits on doses to the public.

The Rules contain an explicit limit on doses to members of the public (He-P 4020.13). Your RPP should address the issue. Basically, He-P 4020.14 says you can evaluate the dose to the individual likely to receive the highest dose from your operations but who is not occupationally exposed (see He-P 4003.01(c1), "occupational dose"). An example might be a receptionist or someone else in a space adjacent to the x-ray room. If the evaluation indicates that individual will not receive a dose exceeding the annual limit of 100 millirem (or if present continually will not receive more than 2 millirem in any one hour nor more than 50 millirem annually), then you are in compliance. Proper shielding is the best single way to meet that requirement and ALARA. Note that He-P 4040.04 requires new facilities, and those modified after August 1998, to have a shielding review and maintain records of it. Installation of a replacement machine would be a modification.

You may reason in your RPP from previous data (e.g., area badge data), other measurements, manufacturer's information, a shielding design, or physical reasoning that your operations are in compliance with the Rules. For instance, suppose you have evidence that occupationally exposed individuals receive annual doses of 100 millirem (or some value of the same order of magnitude) or less. Further suppose the likely maximally non-occupationally exposed individual works several feet further away from the source of scattered radiation than an x-ray operator stands, is out of the direct beam path, and has one or more walls between him or her and the source of radiation. It follows from the physics of the situation that the individual's exposure is less than the applicable limit and that the limit for doses to individual members of the public in general will not be exceeded. Your RPP, or RPP records, should reflect your analysis.

H. Annual reviews of your RPP.

Annual (“not to exceed 12 months”) reviews of your RPP are required by He-P 4020.04(c). Your RPP may contain information:

- saying who is responsible for carrying out and documenting the reviews;
- at what intervals the reviews are to occur (at least annually); and
- any procedures or information needed for conducting the reviews.

You should document your reviews (see Part He-P 4021). How well is your RPP working? Can it be made better? Simpler? Have circumstances changed in any significant way (e.g., an additional machine, an increase in the number of exposures)?

I. Recordkeeping.

Part He-P 4021 covers recordkeeping. There are some additional recordkeeping requirements in other parts of the Rules; see the appendix. Your RPP might identify

- the records to be kept;
- who is responsible for keeping the records;
- where they are kept; and
- how long to keep each record.

Records are to be maintained indefinitely unless there is a provision giving a specific retention time. He-P 4021 gives some specific retention periods.

* * * *

Appendix. Some applicable portions of the New Hampshire Rules for the Control of Radiation.

This list is intended to highlight some portions of the Rules you may wish to become familiar with. Some may be of more interest to you than others, but you should be at least aware of the existence and general import of all of them. The listing is not complete; the omission of any part or section of the Rules from the list below does not mean that it does not apply to your facility, machines, operations, personnel, practices, etc. Compliance with the Rules is the registrant's responsibility.

<u>Reference</u>	<u>Comment</u>
He-P 4001	Scope, exemptions, and provisions: applies to all registrants.
4001.03	Records of receipt, transfer, and disposal of x-ray machines.
4001.04	Inspections.
4001.05	Tests: He-P 4001.05(a) applies.
4001.07	Communications; the Bureau of Radiological Health's address.
4001.08	Units of <u>exposure</u> and dose.
He-P 4003	Definitions; several apply. Be aware that He-P 4041 also contains definitions specifically applicable to x-rays.
He-P 4019	Notices, instructions, and reports to workers; inspections. This is where the requirements for postings appear (He-P 4019.03 (b) through (g).
4019.03(b) through (g)	Postings.
4019.04	Instructions to workers. General requirements on what to tell workers. Remember, school training does not cover things specific to your facility, to your equipment, or to your situation in general. Good training programs will repeat topics from time to time to keep things fresh. There is no required cycle, but an annual period should be sufficient. Keep things simple, but adequate.
He-P 4020	Standards for protection against radiation. Although any section may apply to you, several are not likely to. For instance Sections He-P 4020.06 through 4020.08 deal with internal exposure due to intake of radioactive material and do not apply to the use of x-ray machines.
He-P 4021	Records, reports, and additional requirements.
4021.01	Some general technical requirements on dosimetry results.
4021.02	Records about RPPs.
4021.03	Survey results. He-P 4003(eh) defines "survey" as an evaluation of radiological conditions. Measurements are desirable, but not necessarily required. In light of the public dose limitations of He-P 4020 and the shielding plan review of He-P 4040, this section is applicable.
4021.05	Prior occupational dose. Consider whether you are <u>required</u> to

4021.07	provide individual dosimetry (e.g., film badges). Records of individual monitoring results. If you provide dosimeters, you should keep the data and make it available to your workers.
4021.08	Doses to members of the public.
4021.11	On the form of records.
He-P 4022	Surveys and monitoring.
4022.01	General requirements.
4022.02	Conditions requiring individual monitoring of exposures. It is very unlikely that monitoring of individuals' exposures is necessary in a podiatric practice.
4022.03	Where on the body to wear individual monitoring devices.
4022.10(b)	Control over x-ray machines.
4022.13(d)	The mere presence and use of diagnostic x-ray machines does not necessitate the posting of a "caution" sign.
4022.14(d)	Requires label on x-ray machine cautioning that radiation is produced when the machine is energized.
He-P 4040	Registration of machines and providers of services.
4040.04(a)	Shielding plan review <u>for new and modified facilities</u> . Replacing a machine with a new one is a modification.
4040.04(c)	Things to consider in a shielding review. If you have questions, ask.
4040.05	X-ray machines must be registered with the Bureau of Radiological Health. Notify us 10 days prior to any changes to the information provided in your registration application.
4040.05(g)	Sale of an x-ray machine terminates the registration.
4040.05(j)	You are only to use the services of persons registered with the Bureau of Radiological Health as consultants or as installers and providers of machine services.
4040.07	Registrations are good for up to one year and expire on July 31.
4040.11	Machines in storage. This section explains what to do to be eligible to register a machine as "in storage" for the reduced registration fee.
He-P 4041	Definitions of particular applicability to x-ray machines. Look here as well as in He-P 4003 if you want to see if there is a specific definition of a term used in Parts He-P 4045 or 4046.
He-P 4045	Administrative requirements for the use of x-ray machines.
4045.02 (a) and (b)	General requirements.
4045.03(a)	Don't use a machine that is not compliant with the Rules.
4045.03(b) and (c)	Topics for instruction in procedures and on operators being competent to use <u>your</u> machines.
4045.03(d)	Posting of technique charts for each machine and what the charts are to contain.
4045.03(e)	Written instructions for your workers.
4045.03(f)	On workers being able to demonstrate familiarity with their written

4045.03(m)(7)	safety procedures.
4045.05	Use of grids.
4045.06	Information and maintenance records for each x-ray machine.
4045.07	Patient exposure log.
	On films, film processing, and darkrooms. Protect film, use the correct time and temperature conditions for developing them with chemicals that are adequate in strength and freshness. He-P 4045.07(b)(6) requires some way to prevent accidental entry to a darkroom typically used by more than one person.
He-P 4046	Requirements for x-ray systems.
4046.01	General requirements. He-P 4046.01(a) and (b) require a warning label on the machine. The manufacturer may have put one there.
4046.01(p)	Tube heads must remain stable during exposures.
4046.01(q) through (t)	Indication of technique factors.
4046.01(u)	Certified equipment is to be maintained to meet the federal performance standard.
4046.07	There are things here concerning podiatric machines.
4046.07(n)	A protected area may be a control booth (preferred) or a distance of 2 meters (\approx 6.5 feet) from the machine and out of the direct beam.
He-P 4070	Fees. Sections 4070.01 through 4070.03 and 4070.05 apply to x-ray registrants.
4070.05	Applicable <u>annual</u> fees.
4070.06	Proration of fees is based on the date of acquisition of a machine.